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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,934	07/29/2003	Verivada Chandrasekaran	10527-410002	9045
26161	7590	10/18/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			JACKSON, SUZETTE JAMIE	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,934

Applicant(s)

CHANDRASEKARAN ET AL.

Examiner

Suzette J Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response dated 6/17/04 has been received in application serial number 10/629,934.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2 and 4-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Callol et al. 6,174,329. Callol et al. discloses the invention as claimed noting figures 1-7 comprising: A member (11) including a first portion (14) and a second portion (30, 34) disposed outwardly of the first portion, the second portion being more radiopaque than the first portion and having a first layer (14) including a radiopaque material, and a second layer (30, 34) defining an outer surface of the member and including the radiopaque material and a second material; wherein the second layer comprises an alloy of the radiopaque material (see col.6, line 35-36 *titanium and tantalum* and col. 1, line 64) and the second material; wherein the radiopaque material consist of gold and tantalum (col. 1, lines 61-64); wherein the second material consist of

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titanium (col. 6, lines 35-36); wherein the first portion comprises nickel-titanium alloy (see claim 2); wherein the first portion is the innermost member; wherein the first portion contacts the second portion; in an alternative embodiment illustrating a third portion between the first portion and the second portion (see col. 6, lines 50-54); a polymeric layer on the member (col. 6, lines 24-34).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Callol et al. in view of Roth 2004/0054399. Callol et al. has been disclosed above however Callol et al. does not specify a drug-releasing layer. Roth teaches a stent covered/layered with radiopaque material with a drug releasing layer (see [0032]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of Callol et al. and incorporate therapeutic agents in the layers as taught by Roth in order to treat the vessel intima upon implantation and expansion of the device.

Response to Arguments

6. Applicant's arguments filed 6/17/04 have been fully considered but they are not persuasive. Applicant contends that *"...the material from which Callol et al.'s protective layer is constructed does not include any of the radiopaque material that forms the radiopaque layer....Callol also discloses a radiolucent stent coated with a protective layer that includes radiopaque agents...The protective layer is used as a substitute for rather than a supplement to the radiopaque layer...."* It is the examiners opinion that the applicant has misinterpreted the Callol et al. patent. Callol et al. disclosed a stent coated with a radiopaque material and/or protective layers in varying embodiments. Specifically col. 6, lines 47-54 state: "...Protective coating 40 is loaded with radiopaque agents such as barium, titanium oxide and the like. Further, multiple layers of the protective layer can be applied to the stent where the first layers are loaded with radiopaque agents while the outer most protective layer is not loaded with a radiopaque agent". This clearly meets the limitation that there are first and second layers with radiopaque materials.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

8. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within


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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

10. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Suzette J. Jackson
14 October 2004


David H. Willse
Primary Examiner